

Senate Bill No. 337

Passed the Senate September 4, 2015

Secretary of the Senate

Passed the Assembly September 3, 2015

Chief Clerk of the Assembly

This bill was received by the Governor this _____ day
of _____, 2015, at _____ o'clock ____M.

Private Secretary of the Governor

CHAPTER _____

An act to amend Sections 3501, 3502, and 3502.1 of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 337, Pavley. Physician assistants.

Existing law, the Physician Assistant Practice Act, provides for regulation of physician assistants and authorizes a physician assistant to perform medical services as set forth by regulations when those services are rendered under the supervision of a licensed physician and surgeon, as specified. The act requires the supervising physician and surgeon to review, countersign, and date a sample consisting of, at a minimum, 5% of the medical records of patients treated by the physician assistant functioning under adopted protocols within 30 days of the date of treatment by the physician assistant. The act requires the supervising physician and surgeon to select for review those cases that by diagnosis, problem, treatment, or procedure represent, in his or her judgment, the most significant risk to the patient. A violation of those supervision requirements is a misdemeanor.

This bill would require that the medical record for each episode of care for a patient identify the physician and surgeon who is responsible for the supervision of the physician assistant. The bill would delete those medical record review provisions, and, instead, require the supervising physician and surgeon to use one or more of described review mechanisms. By adding these new requirements, the violation of which would be a crime, this bill would impose a state-mandated local program by changing the definition of a crime.

The act authorizes a physician assistant, while under prescribed supervision of a physician and surgeon, to administer or provide medication to a patient, or transmit orally, or in writing on a patient's record or in a drug order, an order to a person who may lawfully furnish the medication or medical device. The act prohibits a physician assistant from administering, providing, or issuing a drug order to a patient for Schedule II through Schedule V controlled substances without advance approval by a supervising

physician and surgeon for that particular patient unless the physician assistant has completed an education course that covers controlled substances and that meets approved standards. The act requires that the medical record of any patient cared for by a physician assistant for whom a physician assistant's Schedule II drug order has been issued or carried out to be reviewed, countersigned, and dated by a supervising physician and surgeon within 7 days.

This bill would establish an alternative medical records review mechanism, and would authorize the supervising physician and surgeon to use the alternative mechanism, or a sample review mechanism using a combination of the 2 described mechanisms, as specified, to ensure adequate supervision of the administration, provision, or issuance by a physician assistant of a drug order to a patient for Schedule II controlled substances.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 3501 of the Business and Professions Code is amended to read:

3501. (a) As used in this chapter:

- (1) "Board" means the Physician Assistant Board.
- (2) "Approved program" means a program for the education of physician assistants that has been formally approved by the board.
- (3) "Trainee" means a person who is currently enrolled in an approved program.
- (4) "Physician assistant" means a person who meets the requirements of this chapter and is licensed by the board.
- (5) "Supervising physician" or "supervising physician and surgeon" means a physician and surgeon licensed by the Medical Board of California or by the Osteopathic Medical Board of California who supervises one or more physician assistants, who possesses a current valid license to practice medicine, and who is

not currently on disciplinary probation for improper use of a physician assistant.

(6) “Supervision” means that a licensed physician and surgeon oversees the activities of, and accepts responsibility for, the medical services rendered by a physician assistant.

(7) “Regulations” means the rules and regulations as set forth in Chapter 13.8 (commencing with Section 1399.500) of Title 16 of the California Code of Regulations.

(8) “Routine visual screening” means noninvasive nonpharmacological simple testing for visual acuity, visual field defects, color blindness, and depth perception.

(9) “Program manager” means the staff manager of the diversion program, as designated by the executive officer of the board. The program manager shall have background experience in dealing with substance abuse issues.

(10) “Delegation of services agreement” means the writing that delegates to a physician assistant from a supervising physician the medical services the physician assistant is authorized to perform consistent with subdivision (a) of Section 1399.540 of Title 16 of the California Code of Regulations.

(11) “Other specified medical services” means tests or examinations performed or ordered by a physician assistant practicing in compliance with this chapter or regulations of the Medical Board of California promulgated under this chapter.

(12) “Medical records review meeting” means a meeting between the supervising physician and surgeon and the physician assistant during which medical records are reviewed to ensure adequate supervision of the physician assistant functioning under protocols. Medical records review meetings may occur in person or by electronic communication.

(b) A physician assistant acts as an agent of the supervising physician when performing any activity authorized by this chapter or regulations adopted under this chapter.

SEC. 2. Section 3502 of the Business and Professions Code is amended to read:

3502. (a) Notwithstanding any other law, a physician assistant may perform those medical services as set forth by the regulations adopted under this chapter when the services are rendered under the supervision of a licensed physician and surgeon who is not subject to a disciplinary condition imposed by the Medical Board

of California prohibiting that supervision or prohibiting the employment of a physician assistant. The medical record, for each episode of care for a patient, shall identify the physician and surgeon who is responsible for the supervision of the physician assistant.

(b) (1) Notwithstanding any other law, a physician assistant performing medical services under the supervision of a physician and surgeon may assist a doctor of podiatric medicine who is a partner, shareholder, or employee in the same medical group as the supervising physician and surgeon. A physician assistant who assists a doctor of podiatric medicine pursuant to this subdivision shall do so only according to patient-specific orders from the supervising physician and surgeon.

(2) The supervising physician and surgeon shall be physically available to the physician assistant for consultation when that assistance is rendered. A physician assistant assisting a doctor of podiatric medicine shall be limited to performing those duties included within the scope of practice of a doctor of podiatric medicine.

(c) (1) A physician assistant and his or her supervising physician and surgeon shall establish written guidelines for the adequate supervision of the physician assistant. This requirement may be satisfied by the supervising physician and surgeon adopting protocols for some or all of the tasks performed by the physician assistant. The protocols adopted pursuant to this subdivision shall comply with the following requirements:

(A) A protocol governing diagnosis and management shall, at a minimum, include the presence or absence of symptoms, signs, and other data necessary to establish a diagnosis or assessment, any appropriate tests or studies to order, drugs to recommend to the patient, and education to be provided to the patient.

(B) A protocol governing procedures shall set forth the information to be provided to the patient, the nature of the consent to be obtained from the patient, the preparation and technique of the procedure, and the followup care.

(C) Protocols shall be developed by the supervising physician and surgeon or adopted from, or referenced to, texts or other sources.

(D) Protocols shall be signed and dated by the supervising physician and surgeon and the physician assistant.

(2) (A) The supervising physician and surgeon shall use one or more of the following mechanisms to ensure adequate supervision of the physician assistant functioning under the protocols:

(i) The supervising physician and surgeon shall review, countersign, and date a sample consisting of, at a minimum, 5 percent of the medical records of patients treated by the physician assistant functioning under the protocols within 30 days of the date of treatment by the physician assistant.

(ii) The supervising physician and surgeon and physician assistant shall conduct a medical records review meeting at least once a month during at least 10 months of the year. During any month in which a medical records review meeting occurs, the supervising physician and surgeon and physician assistant shall review an aggregate of at least 10 medical records of patients treated by the physician assistant functioning under protocols. Documentation of medical records reviewed during the month shall be jointly signed and dated by the supervising physician and surgeon and the physician assistant.

(iii) The supervising physician and surgeon shall review a sample of at least 10 medical records per month, at least 10 months during the year, using a combination of the countersignature mechanism described in clause (i) and the medical records review meeting mechanism described in clause (ii). During each month for which a sample is reviewed, at least one of the medical records in the sample shall be reviewed using the mechanism described in clause (i) and at least one of the medical records in the sample shall be reviewed using the mechanism described in clause (ii).

(B) In complying with subparagraph (A), the supervising physician and surgeon shall select for review those cases that by diagnosis, problem, treatment, or procedure represent, in his or her judgment, the most significant risk to the patient.

(3) Notwithstanding any other law, the Medical Board of California or the board may establish other alternative mechanisms for the adequate supervision of the physician assistant.

(d) No medical services may be performed under this chapter in any of the following areas:

(1) The determination of the refractive states of the human eye, or the fitting or adaptation of lenses or frames for the aid thereof.

(2) The prescribing or directing the use of, or using, any optical device in connection with ocular exercises, visual training, or orthoptics.

(3) The prescribing of contact lenses for, or the fitting or adaptation of contact lenses to, the human eye.

(4) The practice of dentistry or dental hygiene or the work of a dental auxiliary as defined in Chapter 4 (commencing with Section 1600).

(e) This section shall not be construed in a manner that shall preclude the performance of routine visual screening as defined in Section 3501.

(f) Compliance by a physician assistant and supervising physician and surgeon with this section shall be deemed compliance with Section 1399.546 of Title 16 of the California Code of Regulations.

SEC. 3. Section 3502.1 of the Business and Professions Code is amended to read:

3502.1. (a) In addition to the services authorized in the regulations adopted by the Medical Board of California, and except as prohibited by Section 3502, while under the supervision of a licensed physician and surgeon or physicians and surgeons authorized by law to supervise a physician assistant, a physician assistant may administer or provide medication to a patient, or transmit orally, or in writing on a patient's record or in a drug order, an order to a person who may lawfully furnish the medication or medical device pursuant to subdivisions (c) and (d).

(1) A supervising physician and surgeon who delegates authority to issue a drug order to a physician assistant may limit this authority by specifying the manner in which the physician assistant may issue delegated prescriptions.

(2) Each supervising physician and surgeon who delegates the authority to issue a drug order to a physician assistant shall first prepare and adopt, or adopt, a written, practice specific, formulary and protocols that specify all criteria for the use of a particular drug or device, and any contraindications for the selection. Protocols for Schedule II controlled substances shall address the diagnosis of illness, injury, or condition for which the Schedule II controlled substance is being administered, provided, or issued. The drugs listed in the protocols shall constitute the formulary and shall include only drugs that are appropriate for use in the type of

practice engaged in by the supervising physician and surgeon. When issuing a drug order, the physician assistant is acting on behalf of and as an agent for a supervising physician and surgeon.

(b) “Drug order,” for purposes of this section, means an order for medication that is dispensed to or for a patient, issued and signed by a physician assistant acting as an individual practitioner within the meaning of Section 1306.02 of Title 21 of the Code of Federal Regulations. Notwithstanding any other provision of law, (1) a drug order issued pursuant to this section shall be treated in the same manner as a prescription or order of the supervising physician, (2) all references to “prescription” in this code and the Health and Safety Code shall include drug orders issued by physician assistants pursuant to authority granted by their supervising physicians and surgeons, and (3) the signature of a physician assistant on a drug order shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.

(c) A drug order for any patient cared for by the physician assistant that is issued by the physician assistant shall either be based on the protocols described in subdivision (a) or shall be approved by the supervising physician and surgeon before it is filled or carried out.

(1) A physician assistant shall not administer or provide a drug or issue a drug order for a drug other than for a drug listed in the formulary without advance approval from a supervising physician and surgeon for the particular patient. At the direction and under the supervision of a physician and surgeon, a physician assistant may hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, manufacturer as defined in the Pharmacy Law, or a pharmacist.

(2) A physician assistant shall not administer, provide, or issue a drug order to a patient for Schedule II through Schedule V controlled substances without advance approval by a supervising physician and surgeon for that particular patient unless the physician assistant has completed an education course that covers controlled substances and that meets standards, including pharmacological content, approved by the board. The education course shall be provided either by an accredited continuing education provider or by an approved physician assistant training

program. If the physician assistant will administer, provide, or issue a drug order for Schedule II controlled substances, the course shall contain a minimum of three hours exclusively on Schedule II controlled substances. Completion of the requirements set forth in this paragraph shall be verified and documented in the manner established by the board prior to the physician assistant's use of a registration number issued by the United States Drug Enforcement Administration to the physician assistant to administer, provide, or issue a drug order to a patient for a controlled substance without advance approval by a supervising physician and surgeon for that particular patient.

(3) Any drug order issued by a physician assistant shall be subject to a reasonable quantitative limitation consistent with customary medical practice in the supervising physician and surgeon's practice.

(d) A written drug order issued pursuant to subdivision (a), except a written drug order in a patient's medical record in a health facility or medical practice, shall contain the printed name, address, and telephone number of the supervising physician and surgeon, the printed or stamped name and license number of the physician assistant, and the signature of the physician assistant. Further, a written drug order for a controlled substance, except a written drug order in a patient's medical record in a health facility or a medical practice, shall include the federal controlled substances registration number of the physician assistant and shall otherwise comply with Section 11162.1 of the Health and Safety Code. Except as otherwise required for written drug orders for controlled substances under Section 11162.1 of the Health and Safety Code, the requirements of this subdivision may be met through stamping or otherwise imprinting on the supervising physician and surgeon's prescription blank to show the name, license number, and if applicable, the federal controlled substances registration number of the physician assistant, and shall be signed by the physician assistant. When using a drug order, the physician assistant is acting on behalf of and as the agent of a supervising physician and surgeon.

(e) The supervising physician and surgeon shall use either of the following mechanisms to ensure adequate supervision of the administration, provision, or issuance by a physician assistant of a drug order to a patient for Schedule II controlled substances:

(1) The medical record of any patient cared for by a physician assistant for whom the physician assistant's Schedule II drug order has been issued or carried out shall be reviewed, countersigned, and dated by a supervising physician and surgeon within seven days.

(2) If the physician assistant has documentation evidencing the successful completion of an education course that covers controlled substances, and that controlled substance education course (A) meets the standards, including pharmacological content, established in Sections 1399.610 and 1399.612 of Title 16 of the California Code of Regulations, and (B) is provided either by an accredited continuing education provider or by an approved physician assistant training program, the supervising physician and surgeon shall review, countersign, and date, within seven days, a sample consisting of the medical records of at least 20 percent of the patients cared for by the physician assistant for whom the physician assistant's Schedule II drug order has been issued or carried out. Completion of the requirements set forth in this paragraph shall be verified and documented in the manner established in Section 1399.612 of Title 16 of the California Code of Regulations. Physician assistants who have a certificate of completion of the course described in paragraph (2) of subdivision (c) shall be deemed to have met the education course requirement of this subdivision.

(f) All physician assistants who are authorized by their supervising physicians to issue drug orders for controlled substances shall register with the United States Drug Enforcement Administration (DEA).

(g) The board shall consult with the Medical Board of California and report during its sunset review required by Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code the impacts of exempting Schedule III and Schedule IV drug orders from the requirement for a physician and surgeon to review and countersign the affected medical record of a patient.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty

for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Approved _____, 2015

Governor